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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,324	02/22/2005	Mayumi Saki	506.44793X00	6831

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EXAMINER	
SINGH, ANOOP KUMAR	

ART UNIT	PAPER NUMBER
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/525,324	SAKI ET AL.	
	Examiner	Art Unit	
	Anoop Singh	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-28 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-28 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's preliminary amendments to the claims filed on February 22, 2007 has been received and entered. Claims 6-11, 13-15 have been amended, while claims 23-28 have been added. Claims 1-28 are pending in this application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims, 1-2, 15-16, 20-21, 23-24, drawn to an agent for prevention and/or treatment of itching, which comprises as an active ingredient an oligonucleotide having a antisense oligonucleotide comprising continuous 5 to 60 nucleotides selected from the nucleotide sequence represented by SEQ ID NO: 12, 14, 18 and any oligo that hybridizes with seq ID NO: 12, 14, and 18.

Group II, claim(s) 1, 3, 15-16, 20, 22, 25-26, drawn to an agent for prevention and/or treatment of itching or other disorder, which comprises one of the following 1) to 4) as an active ingredient: 1) an antibody which recognizes a protein having the amino acid sequence represented by SEQ ID NO: 11, 2) SEQ ID NO: 13, 3) SEQ ID NO: 17, and 4) an antibody, which recognizes a protein having amino acid sequence represented by one member selected from SEQ ID NOs:11, 13 and 17.

Group III, claims, 1, 4-9, 10-11, 15-16, 27-28, drawn to an agent comprising nitrogen-containing tricyclic compound represented by the formula (I) or a quaternary ammonium salt thereof.

Group IV, claim, 12, drawn to a method for screening a therapeutic agent for itching comprising administering sphingosyl phosphorylcholine (SPC) subcutaneously

induce scratching behavior in the presence or absence of the test compound to compare the effect in test agent.

Group V, claims, 13,14 and 17 drawn to a method for prevention and/or treatment of itching by administering an effective amount of the nitrogen-containing tricyclic compound.

Group VI, claims, 17 and 18, drawn to a method for prevention and/or treatment of itching by administering a therapeutically effective amount of an antisense.

Group VII, claims, 17 and 19, drawn to a method for prevention and/or treatment of itching by administering a therapeutically effective amount of an antibody.

The inventions listed as Groups I-VII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-VII is an agent for prevention and or itching which is capable of suppressing the function involved in signal transduction of a protein having amino acid sequence represented by SEQ ID NO: 11. Xu et al (WO02/24222, dated 03/28/2002, IDS) teach administration of an effective quantity of a GPR4 antagonist that is efficacious in the management of atopic dermatitis, and that SPC contributes to atopic dermatitis, causing exacerbation. Xu et al teach a method of preventing a disease condition by administering to the patient a therapeutically effective amount of an agent, which interferes with GPR4 (See claims). It is generally known in the art that the skin of a patient with atopic dermatitis reacts abnormally and becomes red, flaky and very itchy. Thus, GPR4 antagonist as dislcosed by cited art would be also effective against alleviating the itching associated wth with atopic dermatitis. Furthermore, claims 1-28 are directed to multiple compositions and methods of using such compositions for prevention of itching and other disorders. Each invention is directed to distinct goal, which comprises the use antisense, chemical agent or antibody in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions encompass multiple composition and methods that do

not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, because they lack the same or corresponding special technical features for the reasons set forth above.

MPEP 1893.03(d) states: If an examiner (1) determines that the claims lack unity of invention and (2) requires election of a single invention, when all of the claims drawn to the elected invention are allowable (i.e., meet the requirements of 35 U.S.C. 101, 102, 103 and 112), the nonelected invention(s) should be considered for rejoinder. Any nonelected product claim that requires all the limitations of an allowable product claim, and any nonelected process claim that requires all the limitations of an allowable process claim, should be rejoined. See MPEP § 821.04 and § 821.04(a). Any nonelected processes of making and/or using an allowable product should be considered for rejoinder following the practice set forth in MPEP § 821.04(b).

Additional restrictions:

For each of Invention I-VII above, restriction to one or more of the following is also required under 35 USC 121. Therefore, election is required of one of Inventions I-VII and one or more of Inventions (A)-(B), as indicated.

If Invention I or VI is elected, elect one of:

(A.) Antisense oligonucleotide comprising continuous 5 to 60 nucleotides selected from the nucleotide sequence represented by SEQ ID NO: 12, 14, 18 and any oligo that hybridizes with seq ID NO: 12, 14, and 18

The antisense oligos listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the oligos lack the same or corresponding special technical features since each of these oligos do not share a common structure feature in common with respect to their structure and binding site. Thus, requirement of unity of invention is not fulfilled.

If Invention II or VII is elected, elect one of:

(B.) antibody which recognizes a protein having the amino acid sequence represented by SEQ ID NO: 11, SEQ ID NO: 13, SEQ ID NO: 17, and amino acid sequence in which one or more amino acid is deleted SEQ ID NOs:11, 13 and 17.

The antibody listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the antibody lack the same or corresponding special technical features since each of these antibody do not share a common structure feature in common with respect to their binding affinity to target peptide and are raised from distinct amino acid sequence. Thus, requirement of unity of invention is not fulfilled.

Election of species:

(a) This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

(C.) R1 represented by plurality of function group substitution as set forth in claim 4. Applicants are required to elect one functional group for each substitution for the structure set forth in claim 4 (I).
(D.) one for one functional group for R3 and R7
(E.) n as 0 or 1
(F.) X as –(CH)2 or –CH=CH-;
(G.) Z1 and Z2 in formula (ii) in claim 4.

Applicant is required, in reply to this action, to elect a single species from A-G to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner: claim 4 and claims dependent therefrom correspond to all the species listed above.

The following claim is generic: 4.

The chemical structure listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the nitrogen-containing tricyclic compound lack the same or corresponding special technical features since each of these nitrogen-containing tricyclic compound do not share a common structure feature in common with respect to their physical and chemical structure. Thus, requirement of unity of invention is not fulfilled.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anoop Singh whose telephone number is (571) 272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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